This listing of claims replaces all prior versions and listings of claims in this application.

LISTING OF CLAIMS:

Claims 1-12 (Canceled)

B2

Claim 13 (Original): A method for preparing a subcutaneously administrable biologically active agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally between said native and denatured states; and

(b) exposing said biologically active agent to a complexing perturbant to reversibility transform said biologically active agent to said intermediate state and to form a subcutaneously administrable supramolecular complex,

said perturbant having a molecular weight ranging from about 150 to about 600 daltons, and having at least one hydrophilic moiety and at least one hydrophobic moiety,

said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent; and

said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for subcutaneous

delivery of said biologically active agent.

Claim 14 (Original): A method as defined in claim 13, wherein said intermediate state has G ranging from about -20 kcal/mole to about 20 kcal/moles relative to said native state.

Claim 15 (Original): A method as defined in claim 13, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 16 (Previously Presented): A method as defined in claim 15, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

Claim 17 (Original): A method as defined in claim 13, wherein said perturbant comprises a proteinoid.

Claim 18 (Original): A method as defined in claim 13, wherein said perturbant is selected from the group consisting of an acylated amino acid and an acylated poly amino acid.

Claim 19 (Original): A method as defined in claim 13, wherein said perturbant is selected from the group consisting of a sulfonated amino acid and a sulfonated poly amino acid.

Claim 20 (Original): A method as defined in claim 13, wherein said perturbant is selected from the group consisting of an acylated aldehyde of an amino acid and an acylated aldehyde of a poly amino acid.

Claim 21 (Original): A method as defined in claim 13, wherein said perturbant is selected from the group consisting of an acylated ketone of an amino acid and an acylated ketone of a poly amino acid.

Claim 22 (Original): A method as defined in claim 13, wherein said perturbant comprises a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

a salt thereof.

Claim 23 (Original): A subcutaneous delivery composition comprising a supramolecular complex comprising:

(a) a biologically active agent in an intermediate conformational state non-covalently complexed with

(b) a complexing perturbant having a molecular weight ranging from about 150 to about 600 and having at least one hydrophilic moiety and at least one hydrophobic moiety;

wherein said intermediate state is reversible to said native state and is conformationally between a native conformational and a denatured conformational state of said biologically active agent and said composition is not a microsphere; and wherein said perturbant is in an amount effective for subcutaneous delivery of said biologically active agent.

Claim 24 (Original): A composition as defined in claim 23, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 25 (Previously Presented): A composition as defined in claim 24, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

Claim 26 (Original): A composition as defined in claim 23, wherein said perturbant comprises a proteinoid.

Claim 27 (Original): A composition as defined in claim 23, wherein said perturbant is selected from the group consisting of an acylated amino acid and an acylated poly amino acid.

Claim 28 (Original): A method as defined in claim 46, wherein said perturbant is selected from the group consisting of a sulfonated amino acid and a

sulfonated poly amino acid.

Claim 29 (Original): A method as defined in claim 23, wherein said perturbant is selected from the group consisting of an acylated aldehyde of an amino acid and an acylated aldehyde of a poly amino acid.

B1
Cont

Claim 30 (Original): A method as defined in claim 23, wherein said perturbant is selected from the group consisting of an acylated ketone of an amino acid and an acylated ketone of a poly amino acid.

Claim 31 (Original): A method as defined in claim 23, wherein said perturbant comprises a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl)naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination

thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

a salt thereof.

Claim 32 (Original): A dosage unit form comprising:

(A) a composition as defined in claim 23; and

B1 Cont

(B) (a) an excipient,

(b) a diluent,

(c) a disintegrant,

(d) a lubricant,

(e) a plasticizer,

(f) a colorant,

(g) a dosing vehicle, or

(h) any combination thereof.

Claim 33 (Original): A method for preparing an agent which is capable of being administered by the subcutaneous route to a subject in need of said agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a complexing perturbant to reversibly transform said biologically active agent to said intermediate state and to form a subcutaneously administrable supramolecular complex,

said perturbant having a molecular weight between about 150 and about 600 daltons, and having at least one hydrophilic moiety and one hydrophilic moiety,

said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent, and

B2 Cont

said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for subcutaneous delivery of said biologically active agent; and

(c) preparing a mimetic of said supramolecular complex.

Claim 34 (Original): A method as defined in claim 33, wherein said biologically active agent comprises a peptide and said mimetic comprises a peptide mimetic.

Claim 35 (Original): A method for preparing an agent which is capable of being administered by the subcutaneous route to a subject in need of said agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate which is

reversible to said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a perturbant to reversibly transform said biologically active agent to said intermediate state, wherein said perturbant is in an amount effective for subcutaneous delivery of said biologically active agent; and

(c) preparing a mimetic of said intermediate state.

Claim 36 (Original): A method as defined in claim 35, wherein said perturbant comprises a pH changing agent, an ionic strength changing agent, or guanidine hydrochloride.

Claim 37 (Currently Amended): A subcutaneous delivery composition comprising a mimetic, the mimetic being a mimetic of ~~the~~ a subcutaneous delivery composition prepared by the method of claim 13.

Claims 38-49 (Canceled)

Claim 50 (Original): A method for preparing a sublingually administrable biologically active agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally

between said native and denatured states; and

(b) exposing said biologically active agent to a complexing perturbant to reversibility transform said biologically active agent to said intermediate state and to form a sublingually administrable supramolecular complex,

said perturbant having a molecular weight ranging from about 150 to about 600 daltons, and having at least one hydrophilic moiety and at least one hydrophobic moiety,

said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent; and

said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for sublingual delivery of said biologically active agent.

Claim 51 (Original): A method as defined in claim 50, wherein said intermediate state has ΔG ranging from about -20 kcal/mole to about 20 kcal/moles relative to said native state.

Claim 52 (Original): A method as defined in claim 50, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 53 (Previously Presented): A method as defined in claim 52,

wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

Claim 54 (Original): A method as defined in claim 50, wherein said perturbant comprises a proteinoid.

Claim 55 (Original): A method as defined in claim 50, wherein said perturbant is selected from the group consisting of an acylated amino acid and an acylated poly amino acid.

Claim 56 (Original): A method as defined in claim 50, wherein said perturbant is selected from the group consisting of a sulfonated amino acid and a sulfonated poly amino acid.

Claim 57 (Original): A method as defined in claim 50, wherein said perturbant is selected from the group consisting of an acylated aldehyde of an amino acid and an acylated aldehyde of a poly amino acid.

Claim 58 (Original): A method as defined in claim 50, wherein said perturbant is selected from the group consisting of an acylated ketone of an amino acid and an acylated ketone of a poly amino acid.

Claim 59 (Original): A method as defined in claim 50, wherein said perturbant comprises a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl)naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

a salt thereof.

Claim 60 (Original): A sublingual delivery composition comprising a

supramolecular complex comprising:

(a) a biologically active agent in an intermediate conformational state non-covalently complexed with

(b) a complexing perturbant having a molecular weight ranging from about 150 to about 600 and having at least one hydrophilic moiety and at least one hydrophobic moiety;

wherein said intermediate state is reversible to said native state and is conformationally between a native conformational and a denatured conformational state of said biologically active agent and said composition is not a microsphere; and wherein said perturbant is in an amount effective for sublingual delivery of said biologically active agent.

B1 cont.

Claim 61 (Original): A composition as defined in claim 60, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 62 (Previously Presented): A composition as defined in claim 61, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin,

desferrioxamine (DFO), low molecular weight heparin, anitmicrobials, or any combination of any of the foregoing.

Claim 63 (Original): A composition as defined in claim 60, wherein said perturbant comprises a proteinoid.

Claim 64 (Original): A composition as defined in claim 60, wherein said perturbant is selected from the group consisting of an acylated amino acid and an acylated poly amino acid.

B1 cont.

Claim 65 (Original): A method as defined in claim 60, wherein said perturbant is selected from the group consisting of a sulfonated amino acid and a sulfonated poly amino acid.

Claim 66 (Original): A method as defined in claim 60, wherein said perturbant is selected from the group consisting of an acylated aldehyde of an amino acid and an acylated aldehyde of a poly amino acid.

Claim 67 (Original): A method as defined in claim 60, wherein said perturbant is selected from the group consisting of an acylated ketone of an amino acid and an acylated ketone of a poly amino acid.

Claim 68 (Original): A method as defined in claim 60, wherein said

perturbant comprises a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl)naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

B1 cont.

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

a salt thereof.

Claim 69 (Original): A dosage unit form comprising:

(A) a composition as defined in claim 60; and

(B) (a) an excipient,

(b) a diluent,

(c) a disintegrant,

(d) a lubricant,

(e) a plasticizer,

(f) a colorant,

(g) a dosing vehicle, or

(h) any combination thereof.

Claim 70 (Original): A method for preparing an agent which is capable of being administered by the sublingual route to a subject in need of said agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a complexing perturbant to reversibly transform said biologically active agent to said intermediate state and to form a sublingually administrable supramolecular complex,

said perturbant having a molecular weight between about 150 and about 600 daltons, and having at least one hydrophilic moiety and one hydrophilic moiety,

said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent, and

said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for sublingual delivery of

said biologically active agent; and

(c) preparing a mimetic of said supramolecular complex.

Claim 71 (Original): A method as defined in claim 70, wherein said biologically active agent comprises a peptide and said mimetic comprises a peptide mimetic.

Claim 72 (Original): A method for preparing an agent which is capable of being administered by the sublingual route to a subject in need of said agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate which is reversible to said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a perturbant to reversibly transform said biologically active agent to said intermediate state, wherein said perturbant is in an amount effective for sublingual delivery of said biologically active agent; and

(c) preparing a mimetic of said intermediate state.

Claim 73 (Original): A method as defined in claim 72, wherein said perturbant comprises a pH changing agent, an ionic strength changing agent, or guanidine hydrochloride.

Claim 74 (Currently Amended): ~~An oral~~ A sublingual delivery composition comprising a mimetic, the mimetic being a mimetic of ~~the oral~~ a sublingual delivery composition prepared by the method of claim 50.

Claims 75-86 (Canceled)

Claim 87 (Original): A method for preparing an intranasally administrable biologically active agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally between said native and denatured states; and

(b) exposing said biologically active agent to a complexing perturbant to reversibility transform said biologically active agent to said intermediate state and to form an intranasally administrable supramolecular complex,

said perturbant having a molecular weight ranging from about 150 to about 600 daltons, and having at least one hydrophilic moiety and at least one hydrophobic moiety,

said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent; and

said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for intranasal delivery of said

biologically active agent.

Claim 88 (Original): A method as defined in claim 87, wherein said intermediate state has G ranging from about -20 kcal/mole to about 20 kcal/moles relative to said native state.

Claim 89 (Original): A method as defined in claim 87, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 90 (Previously Presented): A method as defined in claim 89, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

Claim 91 (Original): A method as defined in claim 87, wherein said perturbant comprises a proteinoid.

Claim 92 (Original): A method as defined in claim 87, wherein said perturbant is selected from the group consisting of an acylated amino acid and an acylated poly amino acid.

Claim 93 (Original): A method as defined in claim 87, wherein said perturbant is selected from the group consisting of a sulfonated amino acid and a sulfonated poly amino acid.

Claim 94 (Original): A method as defined in claim 87, wherein said perturbant is selected from the group consisting of an acylated aldehyde of an amino acid and an acylated aldehyde of a poly amino acid.

B1 cont

Claim 95 (Original): A method as defined in claim 87, wherein said perturbant is selected from the group consisting of an acylated ketone of an amino acid and an acylated ketone of a poly amino acid.

Claim 96 (Original): A method as defined in claim 87, wherein said perturbant comprises a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl)naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

a salt thereof.

B1 cont

Claim 97 (Original): An intranasal delivery composition comprising a supramolecular complex comprising:

(a) a biologically active agent in an intermediate conformational state non-covalently complexed with

(b) a complexing perturbant having a molecular weight ranging from about 150 to about 600 and having at least one hydrophilic moiety and at least one hydrophobic moiety;

wherein said intermediate state is reversible to said native state and is conformationally between a native conformational and a denatured conformational state of said biologically active agent and said composition is not a microsphere; and wherein said perturbant is in an amount effective for intranasal delivery of said biologically active agent.

Claim 98 (Original): A composition as defined in claim 97, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 99 (Previously Presented): A composition as defined in claim 98, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

B1 cont.

Claim 100 (Original): A composition as defined in claim 97, wherein said perturbant comprises a proteinoid.

Claim 101 (Original): A composition as defined in claim 97, wherein said perturbant is selected from the group consisting of an acylated amino acid and an acylated poly amino acid.

Claim 102 (Original): A method as defined in claim 97, wherein said perturbant is selected from the group consisting of a sulfonated amino acid and a sulfonated poly amino acid.

Claim 103 (Original): A method as defined in claim 97, wherein said perturbant is selected from the group consisting of an acylated aldehyde of an amino acid and an acylated aldehyde of a poly amino acid.

Claim 104 (Original): A method as defined in claim 97, wherein said perturbant is selected from the group consisting of an acylated ketone of an amino acid and an acylated ketone of a poly amino acid.

Claim 105 (Original): A method as defined in claim 97, wherein said perturbant comprises a carboxylic acid having the formula

B1 cont'

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl)naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

a salt thereof.

Claim 106 (Original): A dosage unit form comprising:

(A) a composition as defined in claim 97; and

(B) (a) an excipient,

(b) a diluent,

(c) a disintegrant,

(d) a lubricant,

(e) a plasticizer,

(f) a colorant,

(g) a dosing vehicle, or

(h) any combination thereof.

B1 cont.

Claim 107 (Original): A method for preparing an agent which is capable of being administered by the intranasal route to a subject in need of said agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a complexing perturbant to

reversibly transform said biologically active agent to said intermediate state and to form an intranasally administrable supramolecular complex,

said perturbant having a molecular weight between about 150 and about 600 daltons, and having at least one hydrophilic moiety and one hydrophilic moiety,

said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent, and

said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for intranasal delivery of said biologically active agent; and

(c) preparing a mimetic of said supramolecular complex.

B1 cont.

Claim 108 (Original): A method as defined in claim 107, wherein said biologically active agent comprises a peptide and said mimetic comprises a peptide mimetic.

Claim 109 (Original): A method for preparing an agent which is capable of being administered by the intranasal route to a subject in need of said agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate which is reversible to said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a perturbant to reversibly transform said biologically active agent to said intermediate state, wherein said perturbant is in an amount effective for intranasal delivery of said biologically active agent; and

(c) preparing a mimetic of said intermediate state.

Claim 110 (Original): A method as defined in claim 109, wherein said perturbant comprises a pH changing agent, an ionic strength changing agent, or guanidine hydrochloride.

Claim 111 (Original): An ~~oral~~ intranasal delivery composition comprising a mimetic, the mimetic being a mimetic of ~~the oral~~ an intranasal delivery composition prepared by the method of claim 87.

Claim 112 (Currently Amended): The method of claim ~~55~~ 128, wherein the biologically active agent is human growth hormone.

Claim 113 (Currently Amended): The method of claim ~~55~~ 128, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 114 (Currently Amended): The method of claim ~~55~~ 128, wherein the biologically active agent is insulin.

Claim 115 (Currently Amended): The method of claim ~~55~~ 128, wherein the biologically active agent is heparin.

Claim 116 (Currently Amended): The method of claim ~~55~~ 128, wherein the biologically active agent is low molecular weight heparin.

Claim 117 (Currently Amended): The method of claim ~~55~~ 128, wherein the biologically active agent is calcitonin.

Claim 118 (Currently Amended): The method of claim ~~55~~ 128, wherein the biologically active agent is cromolyn sodium.

B1 cont.

Claim 119 (Currently Amended): The method of claim ~~55~~ 128, wherein the biologically active agent is an antimicrobial.

Claim 120 (Currently Amended): The composition of claim ~~64~~ 129, wherein the biologically active agent is human growth hormone.

Claim 121 (Currently Amended): The composition of claim ~~64~~ 129, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 122 (Currently Amended): The composition of claim ~~64~~ 129, wherein the biologically active agent is insulin.

Claim 123 (Currently Amended): The composition of claim ~~64~~ 129, wherein the biologically active agent is heparin.

Claim 124 (Currently Amended): The composition of claim ~~64~~ 129, wherein the biologically active agent is low molecular weight heparin.

Claim 125 (Currently Amended): The composition of claim ~~64~~ 129, wherein the biologically active agent is calcitonin.

Claim 126 (Currently Amended): The composition of claim ~~64~~ 129, wherein the biologically active agent is cromolyn sodium.

B1 cont.

Claim 127 (Currently Amended): The composition of claim ~~64~~ 129, wherein the biologically active agent is an antimicrobial.

Claim 128 (New): A method as defined in claim 55, wherein said perturbant is an acylated amino acid.

Claim 129 (New): A composition as defined in claim 64, wherein said perturbant is an acylated amino acid.

Claim 130 (New): A method as defined in claim 128, wherein the biologically active agent is a peptide.

Claim 131 (New): A method as defined in claim 130, wherein the biologically active agent is an interferon.

Claim 132 (New): A method as defined in claim 130, wherein the biologically active agent is erythropoietin.

Claim 133 (New): A method as defined in claim 130, wherein the biologically active agent is an antigen.

Claim 134 (New): A composition as defined in claim 129, wherein the biologically active agent is a peptide.

B1 cont.

Claim 135 (New): A composition as defined in claim 134, wherein the biologically active agent is an interferon.

Claim 136 (New): A composition as defined in claim 134, wherein the biologically active agent is erythropoietin.

Claim 137 (New): A composition as defined in claim 134, wherein the biologically active agent is an antigen.

Claim 138 (New): A method as defined in claim 18, wherein said perturbant is an acylated amino acid.

Claim 139 (New): The method of claim 138, wherein the biologically active agent is human growth hormone.

Claim 140 (New): The method of claim 138, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 141 (New): The method of claim 138, wherein the biologically active agent is insulin.

Claim 142 (New): The method of claim 138, wherein the biologically active agent is heparin.

B1 cont'

Claim 143 (New): The method of claim 138, wherein the biologically active agent is low molecular weight heparin.

Claim 144 (New): The method of claim 138, wherein the biologically active agent is calcitonin.

Claim 145 (New): The method of claim 138, wherein the biologically active agent is cromolyn sodium.

Claim 146 (New): The method of claim 138, wherein the biologically active agent is an antimicrobial.

Claim 147 (New): A method as defined in claim 138, wherein the biologically active agent is a peptide.

Claim 148 (New): A method as defined in claim 147, wherein the biologically active agent is an interferon.

Claim 149 (New): A method as defined in claim 147, wherein the biologically active agent is erythropoietin.

Claim 150 (New): A method as defined in claim 147, wherein the biologically active agent is an antigen.

B1 cont.

Claim 151 (New): A composition as defined in claim 27, wherein said perturbant is an acylated amino acid.

Claim 152 (New): The composition of claim 151, wherein the biologically active agent is human growth hormone.

Claim 153 (New): The composition of claim 151, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 154 (New): The composition of claim 151, wherein the biologically active agent is insulin.

Claim 155 (New): The composition of claim 151, wherein the biologically active agent is heparin.

Claim 156 (New): The composition of claim 151, wherein the biologically active agent is low molecular weight heparin.

Claim 157 (New): The composition of claim 151, wherein the biologically active agent is calcitonin.

B1 cont.

Claim 158 (New): The composition of claim 151, wherein the biologically active agent is cromolyn sodium.

Claim 159 (New): The composition of claim 151, wherein the biologically active agent is an antimicrobial.

Claim 160 (New): A composition as defined in claim 151, wherein the biologically active agent is a peptide.

Claim 161 (New): A composition as defined in claim 160, wherein the biologically active agent is an interferon.

Claim 162 (New): A composition as defined in claim 160, wherein the biologically active agent is erythropoietin.

Claim 163 (New): A composition as defined in claim 160, wherein the biologically active agent is an antigen.

Claim 164 (New): A method as defined in claim 92, wherein said perturbant is an acylated amino acid.

Claim 165 (New): The method of claim 164, wherein the biologically active agent is human growth hormone.

Claim 166 (New): The method of claim 164, wherein the biologically active agent is growth-hormone releasing hormone.

B1 cont.

Claim 167 (New): The method of claim 164, wherein the biologically active agent is insulin.

Claim 168 (New): The method of claim 164, wherein the biologically active agent is heparin.

Claim 169 (New): The method of claim 164, wherein the biologically active agent is low molecular weight heparin.

Claim 170 (New): The method of claim 164, wherein the biologically active agent is calcitonin.

Claim 171 (New): The method of claim 164, wherein the biologically active agent is cromolyn sodium.

Claim 172 (New): The method of claim 164, wherein the biologically active agent is an antimicrobial.

Claim 173 (New): A method as defined in claim 164, wherein the biologically active agent is a peptide.

Claim 174 (New): A method as defined in claim 173, wherein the biologically active agent is an interferon.

Claim 175 (New): A method as defined in claim 173, wherein the biologically active agent is erythropoietin.

Claim 176 (New): A method as defined in claim 173, wherein the biologically active agent is an antigen.

Claim 177 (New): A composition as defined in claim 101, wherein said perturbant is an acylated amino acid.

Claim 178 (New): The composition of claim 177, wherein the biologically active agent is human growth hormone.

Claim 179 (New): The composition of claim 177, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 180 (New): The composition of claim 177, wherein the biologically active agent is insulin.

Claim 181 (New): The composition of claim 177, wherein the biologically active agent is heparin.

B1 cont

Claim 182 (New): The composition of claim 177, wherein the biologically active agent is low molecular weight heparin.

Claim 183 (New): The composition of claim 177, wherein the biologically active agent is calcitonin.

Claim 184 (New): The composition of claim 177, wherein the biologically active agent is cromolyn sodium.

Claim 185 (New): The composition of claim 177, wherein the biologically active agent is an antimicrobial.

Claim 186 (New): A composition as defined in claim 177, wherein the biologically active agent is a peptide.

Claim 187 (New): A composition as defined in claim 186, wherein the biologically active agent is an interferon.

Claim 188 (New): A composition as defined in claim 186, wherein the biologically active agent is erythropoietin.

Claim 189 (New): A composition as defined in claim 186, wherein the biologically active agent is an antigen.